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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/230,137	08/10/1999	ROBERT WILLIAM CUNNINGHAM	23861-001	4790

7590

10/04/2004

DAVID A JACKSON  
KLAUBER & JACKSON  
411 HACKENSACK AVENUE  
HACKENSACK, NJ 07601

EXAMINER
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CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/230,137

Applicant(s)

CUNNINGHAM

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 27-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 12, 2004 has been entered.

#### *Withdrawal of Rejections from Previous Office Action*

The obviousness rejection over Charlton et al in view of Jenkins et al is withdrawn in view of Applicants' amendment requiring that the throughbore pass entirely through the substrate and the test device leaving the supportive material as the only layer not having a throughbore therein.

#### *Claim Observations*

- Claim 29 is dependent on claim 26, which has been cancelled. The dependency of claim 29 should be changed so that the claim is does not depend from a cancelled claim.

#### *Claim Rejections - 35 USC § 103*

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-6, 9-15, 17-19, 25 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostrup '057 in view of Jenkins et al.

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Ostrup '057 discloses an apparatus for handling biological samples. The apparatus includes a sample collection unit/card (20) comprising a substrate (22) and several apertures (25) that are evenly spaced apart from one another. Absorbent filter paper, i.e. supportive material, (30) is disposed over each aperture. Drops of blood (sample) are applied to the absorbent paper. With respect to claim 3, figure 10 of Ostrup '057 shows two substrates (24, 23), wherein the absorbent material is sandwiched between the two substrates. With respect to claim 4, figures 7-9 show a plurality of spaced apart apertures (25). The card is provided with a bar code (29) for identifying the sample, as recited in claim 18. Regarding claim 6, the sample collection card has a handle portion that allows an automatic apparatus to easily access the collected sample. With respect to claim 13, Ostrup teaches that the sample disk to be used in analysis has a diameter of 5mm (col. 3, lines 48-50). Ostrup '057 also discloses an assembly for the sample collection card, shown by figure 6 and a package shown by figure 8.

Ostrup '058 does not teach a guide means having a sample deposition portion connected to a channel portion and a sample collection means as a part of the kit.

Jenkins et al teach a device for collecting a fluid sample. The device has an aperture in a support member, with an absorbent member attached to the support. Fluid sample is applied through the aperture (32) and is deposited on the absorbent material (52). Downstream from where the sample is deposited, there exists an indicator reagent (56), which provides a color change when enough sample has been taken up by the absorbent material (col. 6, lines 59-65). The user will observe the color change to determine when enough sample is present, as recited in claims 1, 17 and 31. With respect to claims 9 and 10, Jenkins et al teach an aperture (36) located over the indicator to allow the user to view any color change. With respect to claim 11, figure 10 of Jenkins et al shows the indicator (56) absorbed onto the absorbent material.

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Regarding claims 14-15, Jenkins et al teach using cotton for the absorbent material (col. 3, lines 37-38). With respect to claims 19-25, Jenkins et al teach a pouch (80) to contain the device.

It would have been obvious to one of ordinary skill in the art to use incorporate a guide means into the device of Ostrup having an indicator to denote when sufficient sample has been collected. The indicator would allow the user to easily determine that an adequate amount of sample has been collected. Further, with respect to the kit, it would have been obvious to incorporate a means for obtaining the sample, such as a lancet, into the kit. This would allow the user to collect the sample, e.g. draw blood in a safe, effective manner.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Ostrup and Jenkins et al.

4. Claims 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostrup in view of Jenkins et al as applied to claims 1-6, 9-15, 17-19, 25 and 27-31 above, and further in view of US Patent 4,687,529 to Wang.

The disclosures of Ostrup and Jenkins et al are described above. The references differ from the instantly claimed invention in that neither reference teaches incorporating a hydrophobic material as a part of the supportive material.

Wang teaches an absorbent material to be used in a sample collection and test device whereby the absorbent matrices (13, 14, 15) onto which the sample is disposed are separated from one another by hydrophobic materials (17, 18). The hydrophobic materials include waxes (col. 7, lines 23-47). Wang teaches that including the hydrophobic materials between the absorbent matrices eliminates cross contamination between the matrices and problem

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associated with runover of the sample. Thus, it would have been obvious to one of ordinary skill in the art to incorporate hydrophobic materials in between the absorbent materials of Ostrup to prevent any cross contamination of the sample collected on the absorbent material.

5. Claims 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostrup in view of Jenkins et al as applied to claims 1-6, 9-15, 17-19, 25 and 27-31 above, and further in view of US Patent 5,520,041 to Haswell.

The disclosures of both Ostrup and Jenkins et al are described above. Ostrup and Jenkins et al differ from the instant invention in that there is no disclosure of a desiccant in the test kit.

Haswell teaches a collection kit for collecting a blood sample. The kit, like Ostrup, includes a card onto which a blood sample is collected. Haswell teaches that in returning the sample card to the laboratory, the card is put into a packet which contains a desiccant to absorb moisture in the packet during transport. It would have been obvious to one of ordinary skill in the art to incorporate a desiccant into the test kit of Ostrup to help preserve the collected sample and assure the integrity of the sample during testing.

### ***Response to Arguments***

6. Applicant's arguments with respect to claims 1-25 and 27-31 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256.


The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700